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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1627	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,780	ESTEVE-SOLER ET AL.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/26/2005, 6/8/2005, 9/28/2006, 12/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 have been cancelled. Claims 26-44 are pending and are being examined on the merits herein.

Application Priority

This application is the National Stage of International Application No. PCT/EP2003/013468, International Filing Date, 29 November 2003, which designated the United States of America, and which international application was published under PCT Article 21(2) as WO Publication No. WO 2004/050074 A1 and which claims priority from Spanish Application No. 200202754, filed 29 November 2002.

Information Disclosure Statement

The information disclosure statements (IDS) filed on 12/11/2006, 9/28/2006, 6/8/2005, 5/26/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is being considered by the Examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-44 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-44 are directed to the use of a composition in the manufacture of a medicament for treatment and/or prophylaxis of sexual dysfunction, but since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Note: For examination purposes the use claims are interpreted as method of manufacture of the medicament and method of treating sexual dysfunction.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,147,112 ('112).

Claims 26-30 of the instant application are directed to the use of 2, 5 dihydroxybenzenesulfonic compounds for the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in human and is administered in a daily dose of less than 500 mg.

Claims 1-5 of the patent '112 teaches a method of treating sexual dysfunction comprising administering 2, 5 dihydroxybenzenesulfonic compound in an amount between 0.5-2.0 g/day.

At the time of the invention one of ordinary skill in the art would have found it obvious to have used 2, 5 dihydroxybenzenesulfonic compounds for the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in human because of the teachings of the patent '112. It would have been obvious to one having ordinary skill in the art at the time of the invention to have administered less than 0.5 mg per day because the patent '112 teaches administering 0.5 mg. It is well within the skill of an ordinary artisan to optimize the amounts of the drug in a method of treatment in view of attaining optimal therapeutic benefits.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent '112 teaches the use of 2, 5 dihydroxybenzenesulfonic compounds in treating sexual dysfunction.

Claims 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,403, 643 ('643).

Claims 26-30 of the instant application are directed to the use of 2, 5 dihydroxybenzenesulfonic compounds for the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in human and is administered in a daily dose of less than 500 mg.

Claims 1-5 of the patent '643 teaches a method of treating sexual dysfunction comprising administering 2, 5 dihydroxybenzenesulfonic compound in an amount between 0.5-2.0 g/day.

At the time of the invention one of ordinary skill in the art would have found it obvious to have used 2, 5 dihydroxybenzenesulfonic compounds for the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in human because of the teachings of the patent '643. It would have been obvious to one having ordinary skill in the art at the time of the invention to have administered less than 0.5 mg per day because the patent '643 teaches administering 0.5 mg. It is well within the skill of an ordinary artisan to optimize the amounts of the drug in a method of treatment in view of attaining optimal therapeutic benefits.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent '643 teaches the use of 2, 5 dihydroxybenzenesulfonic compounds in treating sexual dysfunction.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide enablement for the prophylaxis of sexual dysfunction in humans comprising a compound of Formula I, a pharmaceutically acceptable solvate. The term "prophylaxis" is defined as a measure taken in prevention of a disease".

Attention is directed to *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and, (8) the quantity of experimentation necessary.

(1, 5) The nature of the invention and the Breadth of the Claims:

The instant claims are drawn to the use of 2, 5 dihydroxybenzenesulfonic compounds of general formula I of claim 26 in the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in humans. The claims are broad with respect to the sexual dysfunction disorders. The breadth of the claims includes compound of formula I as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

(***2) The state of the prior art:***

The specification teaches that W097137647 discloses the use of 2,5-dihydroxybenzenesulfonic compounds for the manufacture of medicaments intended for the normalization of endothelial function, for the treatment of sexual dysfunction, vascular complications of diabetes and for treatment of vascular disorders of endothelial origin. Angulo et al. teaches potentiation of endothelium derived hyperpolarizing factor-mediated relaxation of human penile resistance arteries by calcium dobesilate (Applicant cited IDS: Brit J of Pharmacology, 2003, 139, 854-862). Angulo et al teaches endothelium-dependent relaxation of human penile vascular tissues mediated by NO and EDHF (Applicant cited IDS: BBRC, 312, 2003, 1202-08).

(3) The relative skill of those in the art:

The relative skill of those in the pharmaceutical development and medical treatment arts is high, requiring advanced education and training.

(4) The predictability of the art:

Despite the advanced training of practitioners in the art, it is still impossible to predict from the structure of compounds and from its functionality that all the compounds of formula I claimed will be useful in preventing a sexual disorder. Absent a mechanistic link between the method steps and the observed effect, the pharmaceutical and medical treatment arts are highly unpredictable. Most progress is established through empirical and anecdotal evidence as to the efficacy of certain treatments. Once a mechanistic link has been established between the method and the mechanism of action become more predictable. However, many uncertainties can still exist even when the mechanism of action is known. For example, factors such as the bioavailability, pharmacokinetic profile, and potency of a compound can still be uncertain even if it can be expected to be active in disease models. Applicants in the specification (examples) teach the effects of calcium dobesilate on erectile responses in anesthetized rats. However, it is not predictable from such results that claimed compounds would prevent sexual dysfunction in humans.

(6, 7) The amount of guidance given and the presence of working examples:

The specification provides guidance to the processes for the preparation of active compounds and teaches the steps of making pharmaceutical compositions, teach the effects of calcium dobesilate on erectile responses in anesthetized rats. The specification does not provide any guidance towards prevention (prophylaxis) of the

sexual dysfunction in humans comprising administering 2, 5 dihydroxybenzenesulfonic compounds of general formula I.

(8) The quantity of experimentation necessary:

Given that the instant claims encompass complete prophylaxis or prevention of a sexual dysfunction disorder in humans the guidance of the specification is towards making compounds of formula I, compositions, animal modes for treating erectile dysfunction. Applicants' have not provided any methods to prevent (prophylaxis) the disease or disorder associated with sexual dysfunctions in humans. The burden of enabling the prevention of a disorder would be much greater than that of enabling the treatment of such conditions. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing of such conditions or how a patient could be kept from every being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing (prophylaxis) the above conditions. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Accordingly the claims are evaluated as a method for treating a sexual dysfunction disorder and not as a method for preventing such disorders or diseases.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for making pharmaceutical compositions of the compounds of formula 1 by way of reference to the prior art, does not reasonably provide enablement for making solvates of the compounds of formula I. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. "The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

(1) The nature of the invention: The invention is directed to the use of 2, 5 dihydroxybenzenesulfonic compounds of general formula I of claim 26 in the manufacture of a medicament for the prophylaxis and/or treatment of sexual dysfunction in humans.

(2) The presence or absence of working examples: There are no working

examples provided in the specification with the solvates of compounds of formula I.

(3) The amount of direction or guidance presented: There is no guidance or direction provided in the specification in regards to preparation of the solvates of the compounds of the present invention

(4) The relative skill of those in art: The relative skill of those in the art is high and includes skilled chemists.

(5) The state of the prior art and (6) unpredictability and predictability of the art: The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometery of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or

even the moisture of the air that might change the stabile region of the solvate.

(7) The breadth of the claims: The breadth of the claims includes compound of formula I as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

(8) The quantity of experimentation necessary: Considering the above-mentioned factors and the fact that in the absence of experimentation that one cannot predict if a particular solvent will solvate any particular crystal or not and the stoichiometery of the formed solvate cannot be predicted, the unpredictable nature of art, and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine all the possible solvates. Accordingly, the entire scope of the instant claims is not enabled. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteve-Solver (Applicant cited IDS: WO 97/37647, Corresponding U. S Patents are 6,147,112, 6,403, 643).

Esteve-Solver discloses the use of 2,5-dihydroxybenzenesulfonic compounds for the manufacture of medicaments intended for the normalization of endothelial function, for the treatment of sexual dysfunction, vascular complications of diabetes and for treatment of vascular disorders of endothelial origin (See abstract, p 8-9 claims). The reference teaches an administration of an amount of 0.5-2.0 mg/day of the compounds claimed for normalizing endothelial function.

The reference fails to teach administration of a daily dose of less than 500 mg. of the claimed compounds of formula I for the treatment.

It would have been obvious to one having ordinary skilled in the art at the time of the invention to have used 2, 5 dihydroxy benzenesulfonic compounds in a method of treating sexual dysfunctions because of the teachings of Esteve-Solver. Amount or dosage of drugs is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that

would be obvious for a person of ordinary skill in the art to employ. At the time of the invention one having ordinary skilled in the art would have found it obvious to administer an amount less than 500 mg to treat sexual dysfunctions because it is well within the skilled medical professional to determine suitable dosing regimens. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention. Also, a person of ordinary skill in the art would have been motivated to administer less amount of the drug which has been known in the prior art in treating sexual dysfunction to reduce the side effects, drug interactions and cost of medications.

Claims 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteve-Solver (Applicant cited IDS: WO 97/37647, Corresponding U. S Patents are 6,147,112, 6,403, 643) as applied to claims 26-35 above and in view of Porter (Coating of Pharmaceutical Dosage Forms, chapter 93, 1650-59).

Esteve-Solver teachings discussed as above.

The reference does not teach that the medicament comprising at least one of the compounds of formula I (claim 26) is in a sustained release dosage form.

Porter teaches coating of pharmaceutical dosage forms and states a variety of reasons to coat the active component ranging from esthetic to a desire to control the bioavailability of the drug. The reference describes the pharmaceutical coating processes in p 1650-51. The reference in p 1653, col. 1, para 3 (Film coating Raw

materials) teaches the major components in any film-coating formulation consists of a polymer, plasticizer, colorant and solvent. The reference in the same section teaches that typical plasticizers include glycerin, polyethylene glycol etc and further teaches that the incorporation of a plasticizer into the formulation improves the flexibility of the coating, reduces the risk of film cracking and possibly improves adhesion of film to the substrate. The reference under "Modifies Release Film Coatings" teaches that film coatings applied to pharmaceutical products modify drug release. The reference discusses about both types of releases – delayed (enteric coatings) and extended (sustained or controlled release film coating). The reference discloses the components suitable in sustained release coatings as mixtures of waxes (beeswax, caranauba wax etc.) ethylcellulose polymer, acrylic resins, cellulose acetate (p 1654, col.1). It is known in the prior art (http://en.wikipedia.org/wiki/Acrylic_resin) that acrylic resins include polymethylacrylate. For example, Eudargrit polymer is a polymethylacrylate co-polymer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have formulated a medicament comprising at least one of the compounds of formula I (claim 26) is in a sustained release dosage form from Porter's teachings. One having ordinary skill in the art at the time of the invention would have been motivated to do so is to modify or control the release rate of the drug to achieve steady therapeutic effects.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Esteve-Solver (Applicant cited IDS: WO 97/37647, Corresponding U. S Patents are 6,147,112,

6,403, 643) as applied to claims 26-35 above and in view of Lim et al. (U.S. 2003/0147952).

Esteve-Solver teachings discussed as above.

The reference does not teach that the medicament comprising at least one of the compounds of formula I (claim 26) that have immediate release coating.

Lim teaches manufacture of dosage forms delivering both immediate and sustained-release drugs with immediate release coating (see abstract, para –7, 10). The reference in para 0010 teaches of formulating an immediate release coat dosage forms.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have formulated a medicament comprising at least one of the compounds of formula I (claim 26) that has immediate release coating from the teachings of Lim et al. One having ordinary skill in the art at the time of the invention would have been motivated to do so is for the drug to be available immediately and to provide early onset of therapeutic activities.

Claims 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esteve-Solver (Applicant cited IDS: WO 97/37647, Corresponding U. S Patents are 6,147,112, 6,403, 643) as applied to claims 26-35 above and in view of Grabowski et al. (Applicant cited IDS: U.S. 6,290,990).

Esteve-Solver teachings discussed as above.

The reference does not teach that the medicament comprising at least one of the compounds of formula I (claim 26) is in a sustained release dosage form.

Grabowski et al. teaches slow release matrix pellets comprising a biologically active compound such as calcium dobesilate, one water insoluble polymer (see abstract, col. 4, line 20). The reference teaches that the natural, semisynthetic or synthetic polymer b) which is insoluble in water and gastrointestinal fluids can be, for example, a cellulose ether such as ethylcellulose, poly(meth)acrylates etc (col. 5, lines 12-20). The reference teaches addition of plasticizers such as polyethylene glycols, poly propylene glycols etc (col. 6, lines 36-43). The reference teaches addition of waxes to the formulation (col. 5, line 25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have formulated a medicament comprising at least one of the compounds of formula I (claim 26) is in a sustained release dosage form from Grabowski et al. teachings. One having ordinary skill in the art at the time of the invention would have been motivated to do so is to modify or control the release rate of the drug at a predetermined rate by maintaining a constant drug level for a specific period of time. The reference Grabowski et al do not specifically teach the wax to be carnauba or beeswax as claimed. However it is well known in the art (Porter, Coating of Pharmaceutical Dosage Forms, chapter 93, 1650-59) that the components suitable in sustained release coatings as mixtures of waxes (beeswax, caranauba wax etc.), Hence it would have been obvious to one having ordinary skill in the art at the time of the invention to have used a wax such as beeswax in sustained released coatings of the pharmaceutical drugs.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

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